

## **REMARKS**

The issues outstanding in the office action mailed March 17, 2009, are the rejections under 35 U.S.C. 112 and 103. The Examiner is thanked for indicating withdrawal of the prior rejection under 35 U.S.C. 102. Reconsideration of the remaining issues, in view of the following discussion, is respectfully requested.

### **Rejection Under 35 U.S.C. 112**

Claim 12 has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. It is argued, at page 2 of the office action, that the recitation of “complete” decellularization of the tissue is not supported. Applicants disagree with this analysis. As noted at page 3 of the office action, the specification states that the methods result in decellularization “even in deep interior portions by irradiation with microwaves.” Moreover, although not cited by the Examiner, page 4, paragraph 6 of the specification criticizes the prior art and teaches that because of prior art limitations, “complete decellularization and removal of bacteria and viruses are hardly possible for large tissue materials.” Later in the paragraph, it is further noted that known treating processes “do not assure complete inactivation of a viral contaminant and infection incidents may often occur from transplanted tissue...”. Paragraph 8 then indicates that it is an object of the invention to provide a method which can “eliminate or ameliorate disadvantages of the prior art, namely, a method which can accomplish, first, removal of cellular components.” Thus, it is submitted that the concept of “complete” decellularization is, in fact, taught, nearly in those words. However, in order to expedite prosecution, the claim has been amended to use the language which can be found at page 11, lines 4-6, stating that the immunogenicity of the tissue is substantially diminished. Further, with respect to amendments to claims 10 and 12, indicating that fixation chemicals are not used, it is evident that the invention optionally involved the use of fixation chemicals, see page 6 and 7, paragraph 14. Since Applicants contemplated the optional use of fixing chemicals, they accordingly have the written description to exclude them. See, for example, *In re Johnson*, 558 F.2d 1008, 194 USPQ 187 (CCPA 1977) and *Ex parte Graselli*, 231 USPQ 394 (POBA 1984,

released 1986) aff'd.

**Rejection Under 35 U.S.C. 103**

Claims 5 and 7-11 have been rejected under 35 U.S.C. 103 over Login taken with Giberson and Boon. Reconsideration of this rejection is again respectfully requested. Login requires the use of a fixation solution, see column 5, lines 9-25. Accordingly, it is submitted that this disclosure fails to suggest independent claims 10 and 12, which recite the absence of a fixation chemical. Accordingly, withdrawal of the rejection is respectfully requested.

The claims of the application are submitted to be in condition for allowance. However, if the Examiner has any questions or comments, he or she is cordially invited to telephone the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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Attorney Docket No.: AKA-0286  
Date: June 17, 2009